

Office of Minority Health Goals and Objectives for Pharmacy Student Rotations

I. Goals:

The purpose of this rotation is to familiarize the student with the role of the Food and Drug Administration (FDA) in drug development, review, and post-marketing phases, with special emphasis on health disparities, data collection and communication/outreach to minority populations.

II. Describe the Learning Objectives:

Upon completion of this rotation the student will be able to:

A. Describe the development of a new drug from laboratory to commercial distribution of the product and the FDA's role in that process and special issues in the recruitment of minorities into clinical trials.

B. Distinguish between the three phases of clinical trials in the drug development process, and understand the necessary data needs and challenges to ensure representativeness of the intended population for assessing safety and efficacy in the context of risk/benefit.

C. Utilize drug information, FDA resources, and online Pub Med literature searches as necessary to research assigned project topic in minority health and drug regulation. The student will work closely with both their preceptor and other professional staff, who will provide guidance and assistance to the student for successful completion of this project.

D. Become familiar with HHS policies, Federal laws, regulations and guidances impacting health disparities and the inclusion of demographic subgroups in clinical trials submitted to FDA, approved labeling for medical products, and communication of FDA actions to minority populations.

III. Student Requirements:

The student will be exposed to a variety of issues regarding aspects of minority health and FDA policies. The program will focus on familiarizing the student with the type of information collected and what is releasable from the FDA. To meet these objectives the student will be expected to:

A. Complete and present to OMH staff a PowerPoint presentation on a topic related to health disparities and FDA regulation. This project topic will be reviewed by the director and is directly related to the information needs at the time of the rotation. In some cases a short project write-up report is required.

B. Attend core student rotation lectures within the Office of the Commissioner and FDA Centers.

C. Fulfill required hours